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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/117,357	09/22/98	STOCKEMANN K	SCH1655

EXAMINER	
DELACROIX MUIRHEI C	
ART UNIT	**PAPER NUMBER**
1614	18

HM12/0604
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DATE MAILED: 06/04/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/117,357	STOCKMANN et al.
Examiner	**Art Unit**
Cybille Delacroix-Muirheid	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *May 14, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *11-16, 20-22, 30, 33-36, and 40-43* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *11-16, 20-22, 30, 33-36, and 40-43* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Continued Prosecution Application

1. The request filed on May 14, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/117,357 is acceptable and a CPA has been established. An action on the CPA follows.

The following is also responsive to the Preliminary amendment received May 14, 2001.

New claims 40-42 have been added. Claims 11-16, 20-22, 30, 33-36 and 40-42 are currently pending.

The previous objection to claim 30, set forth in paragraph 1 of the office action mailed Nov. 13, 2000 **is withdrawn** in view of the preliminary amendment received May 14, 2001.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 34-36, 11-16, 20-22, 30, 33, 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goulding et al.

Goulding et al. disclose a method for studying the effects of the anti-estrogen, Tamoxifen, on bone loss in rats treated with buserelin, an LHRH agonist. Specifically, Goulding et al. studied such effects by treating rats with 25 μg/kg body weight of buserelin and 20 mg/kg body weight of Tamoxifen (Group D) and monitoring the bone resorption. Results prove that Tamoxifen slowed bone loss and bone-thinning effects of buserelin in the rats. In view of the results, Goulding et al. suggest that the bone protecting effects of Tamoxifen should be studied in women undergoing LHRH agonist therapy. Please refer to the abstract; page 147, Fig. 2; page 148, Discussion, first full paragraph.

Goulding et al. do not specifically disclose a method of administering buserelin and Tamoxifen to a human patient; however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Goulding to include human patients, especially women, because the desirable results provided by the Goulding et al. study prove that

Tamoxifen is successful in inhibiting the inherent bone-thinning effects of buserelin in rats. Such a modification would have been motivated by the reasoned expectation of preventing the bone-thinning effects of buserelin which are also observed in human patients, particularly women. Moreover, Goulding et al. teaches that Tamoxifen is known to slow bone loss in post-menopausal women because it acts as an estrogen agonist in the skeleton. Please see the abstract; page 148, Discussion, last four lines to page 149 line 2.

Concerning claims 12, 15, 16, 21, 35, 41-43 which claim administration of anti-estrogens (Raloxifen, Droloxifen and Centchroman) other than Tamoxifen, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute Tamoxifen with these other anti-estrogens because, absent evidence to the contrary, one of skill in the art would reasonably expect the claimed anti-estrogens to have similar properties as Tamoxifen.

In addressing claims 13, 20, 30, 33, 40, 42 and 43 modification of the method in Goulding et al. to administer buserelin orally as well as the use of LHRH antagonists or peptidergic LHRH analogues in the method of Goulding would have been obvious and well within the capability of the skilled artisan. Moreover, one of ordinary skill in the art would expect the specific LHRH analogues of the claims to be equally effective in ameliorating bone loss.

Finally, since Goulding et al. establish that the effect of Tamoxifen is dose dependent, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the dose of Tamoxifen in the Goulding et al. study so as to optimize its inhibiting effect against buserelin.

Conclusion

Claims 11-16, 20-22, 30, 33-36 are rejected.

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bryant et al., 6,096,764.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM

May 31, 2001

Cybille Delacroix-Muirheid
Patent Examiner Group 1600